Respirator Audit Logic Concept
April 27, 2006

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Respirator Audit Logic Concept

A Respirator Audit Logic Concept is being proposed by the National Personal Protective Technology Laboratory (NPPTL) Technology Evaluation Branch (TEB) in selecting NIOSH-approved respirators for product audit utilizing the Respirator Audit Logic systematic approach. Respirator product audits are obtained on consignment from the manufacturer, open market, or obtained during a manufacturing site audit. These samples are performance-tested and verified for conformance to the NIOSH approval. The Respirator Audit Logic for Respirator Product Audits is designed to give the highest priority to those respirator approvals which, based on the past performance and other characteristics, are most likely to pose a public health risk to workers.

Respirator Product Audits

- **Each year the Technology Evaluation Branch conducts product audits of NIOSH-certified respirators which include private labels.**

- **Selected NIOSH certification tests are performed on these samples and a product verification conducted to determine if the approved respirator continues to meet the applicable requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR Part 84)**

- **These Respirator Product Audits are conducted under the authority of 84.65(e) and 84.42(c). NIOSH has traditionally exercised this right in obtaining product audit samples for post-certification evaluation and surveillance of NIOSH- approved respiratory equipment.**

Respirator Audit Logic Concept

- **Benefits to Manufacturers**
  - More systematic approach
  - Unbiased selection
  - Less products audits for low risk, high quality manufacturers
  - Validation of quality plan

- **Benefits to the Consumer**
  - Minimize consumer risk
  - Assurance of expected performance
  - Maintains integrity of approval

- **Benefits to NIOSH**
  - More systematic approach
  - More accurate and consistent database
  - Improving the surveillance of NIOSH approved respiratory equipment
  - Validation of quality plan

Respirator Audit Factor (RAF)

- **Products to be audited are determined by computing a Respirator Audit Factor (RAF) and selecting products from a prioritized list**

- **The RAF is determined by evaluating the 11 categories described, combined with ranking factors using a mathematical formula**

- **Categories – These represent various parameters determined by the Technology Evaluation Branch to be the most essential in providing a RAF. The results of the data compiled for each category is used in the selection of the respirator product audits.**

- **Weighting Factors – These are numerical values assigned to each category. The higher values indicate the weighing factors determined by the Technology Evaluation Branch to be most significant.**

Respirator Audit Factor - continued

- **The Respirator Audit Factors are computed using the formula:**

$$RAF = \sum_{n=1}^{n=11} F^n C^n$$

- **Where C1 through C11 are the numerical values for each category**

- **F1 through F11 are the weighting factors (importance) assigned to each category**

Respirator Audit Factor (RAF)

- **<u>Categories</u>** – **These represent various parameters determined by the Technology Evaluation Branch to be the most essential in providing a RAF. The results of the data compiled for each category is used in the selection of the respirator product audits.**

  C1 = Criticality of Product Approvals (CBRN/IDLH, Other Approvals) – Represents respirator classes such as Air Supplied and Air Purifying respirators

  C2 = Site Audit History – Represents the results from the most recent onsite audit report

  C3 = Product Audit History – Represents the results from of the most recent product audit report for each approval

  C4 = Field Problem/Complaint History – Represents the results the most recent verified field problem report for each approval, if applicable

  C5 = Number of Approvals – Represents the number of Manufacturer's NIOSH Approvals

  C6 = Percentage of Approvals Audited – Represents the percentage of Manufacturer's NIOSH approvals that have been audited in the last 10 years

Respirator Audit Factor (RAF)

- **Categories** – These represent various parameters determined by the Technology Evaluation Branch to be the most essential in providing a RAF. The results of the data compiled for each category is used in the selection of the respirator product audits.

    C7 = Application Denial/Withdrawal History – Represents the complied in house application denial/withdrawal history based on test failures and quality assurance discrepancies for all respirator manufacturers throughout the year.

    C8 = Percentage of New Product Approvals – Represents in house the quantity of new or extension of approvals which were granted based on a percentage of total approvals held

    C9 = Test Result Correlation Factor = Represents the manufacturers test data as compared to the NIOSH test report findings for both new and extension of approval applications

    C10 = Stop Sales/Recall/Retrofit within the last year = Represents all products approvals from the manufacturer that have been issued a recent stop sale, recall, or retrofit letters issued for the product. This includes any self reporting by the manufacturers to NIOSH

    C11 = ISO Registered Facility = Represents the status of approval holder manufacturer sites

- **Weighting Factors** – These are numerical values assigned to each category. The higher values indicate the weighting factors determined by the Technology Evaluation Branch to be most significant.

Concept Respirator Audit Logic

(C1*P1 + C2*F2 + C3*F3 + C4*F4 + C5*F5 + C6*F6 + C7*F7 + C8*F8 + C9*P9 + C10*P10 + C11*P11)= Respirator Audit Factor (RAF)

TC#	Protection	Mfr	C1 Criticality of Product Approvals P1=6	C2 Site Audit History F2=8	C3 Product Audit History F3=12	C4 Field Problem Complaint History F4=10	C5 Number of Approvals F5=4	C6 Percentage of Approvals Audited F6=5	C7 Application Denial Withdrawal History F7=10	C8 Percentage of Product Approvals F8=10	C9 Test Result Correlation Factor P9=10	C10 Stop Sales Recall Retrofit within last Year P10=20	C11 ISO Registered Facility P11=5	Audit Factor	Test Selection
84A-XXXX	MA/AM	ABC	60	80	120	100	40	50	100	100	100	200	50	1000	
84A-AAAA	CL	XYZ	12	32	60	50	16	20	90	70	90	180	20	640	
13F-XXXX	SCBA	DEF	60	40	72	80	4	10	10	60	30	120	30	516	
19C-ZZZZ	SAR/CF	DDD	20	8	12	20	8	10	40	20	20	60	10	228	

Concept Respirator Audit Logic

$$(C1*P1 + C2*P2 + C3*P3 + C4*P4 + C5*P5 + C6*P6 + C7*P7 + C8*P8 + C9*P9 + C10*P10 + C11*P11) = \text{Respirator Audit Factor (RAF)}$$

TC#	TYPE	Mfr	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	Audit Factor	Test Selection
			Criticality of Product Approvals P1=6	Site Audit History P2=8	Product Audit History P3=12	Field Problem Complaint History P4=10	Number of Approvals P5=4	Percentage of Approvals Audited P6=5	Application Denial Withdrawal History P7=10	Percentage of Product Approvals P8=10	Test Result Correlation Factor P9=10	Stop Sales Recall Retrofit within last Year P10=20	ISO Registered Facility P11=5		
84A-XXXX	AP	ABC	60	80	120	100	40	50	100	100	100	200	50	1000	
84A-AAAA	AP	XYZ	12	32	60	50	16	20	90	70	90	180	20	640	
13F-XXXX	AS	DEF	60	40	72	80	4	10	10	60	30	120	30	516	
19C-ZZZZ	AS	DDD	20	8	12	20	8	10	40	20	20	60	10	228	

OTHER FACTORS

In addition to Respirator Audit Logic (RAL), NIOSH product audits will be conducted for the following reasons:

- New manufacturer receives initial NIOSH approval

- *Approval Holder Manufacturing Sites relocated

- *Respirator product line acquired by another company

- *Site audit not conducted within a five-year time frame

- *No product audits on an individual Manufacturer's NIOSH approvals within the last five years

*The Technology Evaluation Branch will select a representative sample from each classification of respirator.

Additional Audits

- **Additional audits may be conducted pursuant to specific requests by HHS, CDC, or NIOSH.**

- **These products audits will not use the Respirator Audit Logic criteria.**

Respirator Audit Factor (RAF)

Letter to the Manufacturers

- Respirator Protection (OV, P100, AG, CBRN SCBA . . .)

- Mfg Name

- TC Number

- Product Status (Active, inactive, obsolete)

- Approval Holder Mfg Sites

- ISO Registered Facility

Respirator Audit Logic - Application Review

- **Respirator Audit Factors**

  - Information on C1, C2, C3, C4, C6, C7, C8, C10 is currently being required within the DEIMS database

  - The Respirator Audit Logic calculations for (C1 to C11) will be created and incorporated within the DEIMS database

  - Modification to the Standard Application Form will be required to capture necessary or additional information from the manufacturers to support the Respirator Audit Logic

Respirator Audit Factor (RAF)

Phase 1 :

- Post the information for the RAL Concept to the NIOSH/NPPTL website prior to the April 27, 2006 meeting

- Introduce the RAL Concept at the manufacturers' meeting on April 27, 2006

- Receive comments and feedback on the concept by June 2006

- Send a letter to all NIOSH Approval holders to determine production status of approved respirators by July 2006 to be returned by October 2006

Respirator Audit Factor (RAF)

Phase 2

- Develop the DEIMS database
- Input the information received from the manufacturers.
- Incorporate the information for the RAL into the DEIMS database.
- Modify the SAF to incorporate the necessary information related to the RAL

Phase 3

- Validation testing of the RAL to ensure calculation and reporting is correct
- Beta test to selected manufacturers
- Status report to manufacturers
- Implementation of the RAL (Summer 2007)

Please review the Respirator Audit Logic (RAL) document at the following NPPTL Webpage under spotlights and email any comments regarding the document to the NPPTL email address below.

http:// www.cdc.gov/niosh/npptl/default.html

NPPTL@cdc.gov

Questions/Comments?